

110TH CONGRESS
1ST SESSION

S. 1858

To amend the Public Health Service Act to establish grant programs to provide for education and outreach on newborn screening and coordinated followup care once newborn screening has been conducted, to reauthorize programs under part A of title XI of such Act, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JULY 23, 2007

Mr. DODD (for himself, Mr. HATCH, Mrs. CLINTON, and Mr. KENNEDY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Public Health Service Act to establish grant programs to provide for education and outreach on newborn screening and coordinated followup care once newborn screening has been conducted, to reauthorize programs under part A of title XI of such Act, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Newborn Screening
5 Saves Lives Act of 2007”.

1 **SEC. 2. FINDINGS.**

2 Congress finds the following:

3 (1) Each year more than 4,000,000 babies born
4 in the United States are screened by State and pri-
5 vate laboratories to detect some conditions that may
6 threaten their long-term health.

7 (2) However, there is a lack of uniformity in
8 the number of conditions for which newborns are
9 screened throughout the United States. While a new-
10 born may be screened and treated for a debilitating
11 condition in one State, in another State, the condi-
12 tion may go undetected and result in permanent dis-
13 ability or even death.

14 (3) Approximately 4,000 infants born each year
15 are diagnosed with these detectable and treatable
16 disorders. If diagnosed early, these conditions can be
17 successfully managed or treated to prevent severe
18 and often lifelong health consequences.

19 (4) In 2004, the American College of Medical
20 Genetics (ACMG) completed a report commissioned
21 by the Department of Health and Human Services
22 which recommended that every baby born in the
23 United States be screened for 29 specific disorders,
24 including certain metabolic conditions and hearing
25 deficiencies.

1 (5) Currently only 11 States and the District of
 2 Columbia require infants to be screened for all 29 of
 3 these recommended disorders.

4 (6) Continuity, especially during a public health
 5 emergency, plays a critical role in the screening, di-
 6 agnosis, referral, and treatment of these disorders.
 7 Currently there is no national contingency plan for
 8 maintaining continuity of newborn screening systems
 9 following a public health emergency.

10 **SEC. 3. AMENDMENT TO TITLE III OF THE PUBLIC HEALTH**
 11 **SERVICE ACT.**

12 Part Q of title III of the Public Health Service Act
 13 (42 U.S.C. 280h et seq.) is amended by adding at the end
 14 the following:

15 **“SEC. 399Z-1. NEWBORN SCREENING.**

16 “(a) AUTHORIZATION OF GRANT PROGRAMS.—From
 17 funds appropriated under subsection (h), the Secretary,
 18 acting through the Administrator of the Health Resources
 19 and Services Administration (referred to in this section
 20 as the ‘Administrator’) and in consultation with the Advi-
 21 sory Committee on Heritable Disorders in Newborns and
 22 Children (referred to in this section as the ‘Advisory Com-
 23 mittee’), shall award grants to eligible entities to enable
 24 such entities to assist in providing health care profes-

1 sionals and newborn screening laboratory personnel
 2 with—

3 “(1) education in newborn screening; and

4 “(2) training in—

5 “(A) relevant and new technologies in new-
 6 born screening; and

7 “(B) congenital, genetic, and metabolic
 8 disorders.

9 “(b) APPLICATION.—An eligible entity that desires to
 10 receive a grant under this section shall submit an applica-
 11 tion to the Secretary at such time, in such manner, and
 12 accompanied by such information as the Secretary may
 13 require.

14 “(c) SELECTION OF GRANT RECIPIENTS.—

15 “(1) IN GENERAL.—Not later than 120 days
 16 after receiving an application under subsection (b),
 17 the Secretary, after considering the approval factors
 18 under paragraph (2), shall determine whether to
 19 award the eligible entity a grant under this section.

20 “(2) APPROVAL FACTORS.—

21 “(A) REQUIREMENTS FOR APPROVAL.—An
 22 application submitted under subsection (b) may
 23 not be approved by the Secretary unless the ap-
 24 plication contains assurances that the eligible
 25 entity—

1 “(i) will use grant funds only for the
2 purposes specified in the approved applica-
3 tion and in accordance with the require-
4 ments of this section; and

5 “(ii) will establish such fiscal control
6 and fund accounting procedures as may be
7 necessary to assure proper disbursement
8 and accounting of Federal funds paid to
9 the eligible entity under the grant.

10 “(B) EXISTING PROGRAMS.—Prior to
11 awarding a grant under this section, the Sec-
12 retary shall—

13 “(i) conduct an assessment of existing
14 educational resources and training pro-
15 grams with respect to newborn screening;
16 and

17 “(ii) take all necessary steps to mini-
18 mize the duplication of the resources and
19 programs described in clause (i) and en-
20 sure that funding under this section will
21 supplement, not supplant, existing funding
22 for such activities.

23 “(d) COORDINATION.—The Secretary shall take all
24 necessary steps to coordinate programs funded with

1 grants received under this section and to coordinate with
 2 existing newborn screening activities.

3 “(e) USE OF GRANT FUNDS.—An eligible entity that
 4 receives a grant under subsection (a)(1) may use the grant
 5 funds to work with appropriate medical schools, nursing
 6 schools, schools of public health, schools of genetic coun-
 7 seling, internal education programs in State agencies, non-
 8 governmental organizations, and professional organiza-
 9 tions and societies to develop and deliver education and
 10 training programs that include—

11 “(1) continuing medical education programs for
 12 health care professionals and newborn screening lab-
 13 oratory personnel in newborn screening;

14 “(2) education, technical assistance, and train-
 15 ing on new discoveries in newborn screening and the
 16 use of any related technology;

17 “(3) models to evaluate the prevalence of, and
 18 assess and communicate the risks of, congenital con-
 19 ditions, including the prevalence and risk of some of
 20 these conditions based on family history;

21 “(4) models to communicate effectively with
 22 parents and families about—

23 “(A) the process and benefits of newborn
 24 screening and the meaning of screening results,

1 including the possibility of false positive find-
 2 ings;

3 “(B) how to use information gathered from
 4 newborn screening;

5 “(C) the right of refusal of newborn
 6 screening, if applicable; and

7 “(D) the potential need for followup care
 8 after newborns are screened;

9 “(5) information and resources on coordinated
 10 systems of followup care after newborns are
 11 screened;

12 “(6) information on the disorders for which
 13 States require and offer newborn screening and op-
 14 tions for newborn screening relating to conditions in
 15 addition to such disorders;

16 “(7) information on additional newborn screen-
 17 ing that may not be required by the State, but that
 18 may be available from other sources; and

19 “(8) other items to carry out the purpose de-
 20 scribed in subsection (a)(1) as determined appro-
 21 priate by the Secretary.

22 “(f) REPORTS TO CONGRESS.—

23 “(1) IN GENERAL.—Subject to paragraph (2),
 24 the Secretary shall submit to the relevant commit-
 25 tees of Congress reports—

1 “(A) evaluating the effectiveness and the
2 impact of the grants awarded under this sec-
3 tion—

4 “(i) in promoting newborn screening
5 education, resources, and training for
6 health care professionals;

7 “(ii) on the successful diagnosis and
8 treatment of congenital, genetic, and meta-
9 bolic disorders; and

10 “(iii) on the continued development of
11 coordinated systems of followup care after
12 newborns are screened;

13 “(B) describing and evaluating the effec-
14 tiveness of the activities carried out with grant
15 funds received under this section; and

16 “(C) that include recommendations for
17 Federal, State, and local actions to support—

18 “(i) education and training in new-
19 born screening; and

20 “(ii) followup care after newborns are
21 screened.

22 “(2) TIMING OF REPORTS.—The Secretary shall
23 submit—

24 “(A) an interim report that includes the
25 information described in paragraph (1), not

1 later than 30 months after the date on which
 2 the first grant funds are awarded under this
 3 section; and

4 “(B) a subsequent report that includes the
 5 information described in paragraph (1), not
 6 later than 60 months after the date on which
 7 the first grant funds are awarded under this
 8 section.

9 “(g) DEFINITION OF ELIGIBLE ENTITY.—In this sec-
 10 tion, the term ‘eligible entity’ means—

11 “(1) a State or a political subdivision of a
 12 State;

13 “(2) a consortium of 2 or more States or polit-
 14 ical subdivisions of States;

15 “(3) a territory;

16 “(4) an Indian tribe or a hospital or outpatient
 17 health care facility of the Indian Health Service; or

18 “(5) other entities with appropriate expertise in
 19 newborn screening, as determined by the Secretary.

20 “(h) AUTHORIZATION OF APPROPRIATIONS.—There
 21 are authorized to be appropriated to carry out this sec-
 22 tion—

23 “(1) \$5,000,000 for fiscal year 2008; and

24 “(2) such sums as may be necessary for each
 25 of fiscal years 2009 through 2012.”.

1 **SEC. 4. IMPROVED NEWBORN AND CHILD SCREENING FOR**
2 **HERITABLE DISORDERS.**

3 Section 1109 of the Public Health Service Act (42
4 U.S.C. 300b–8) is amended—

5 (1) in subsection (c)(2)—

6 (A) in subparagraph (E), by striking
7 “and” after the semicolon;

8 (B) by redesignating subparagraph (F) as
9 subparagraph (G); and

10 (C) by inserting after subparagraph (E)
11 the following:

12 “(F) an assurance that the entity has
13 adopted and implemented, is in the process of
14 adopting and implementing, or will use grant
15 amounts received under this section to adopt
16 and implement the guidelines and recommenda-
17 tions of the Advisory Committee on Heritable
18 Disorders in Newborns and Children established
19 under section 1111 (referred to in this section
20 as the ‘Advisory Committee’) that are adopted
21 by the Secretary and in effect at the time the
22 grant is awarded or renewed under this section,
23 which shall include the screening of each new-
24 born for the heritable disorders recommended
25 by the Advisory Committee and adopted by the

1 Secretary and the reporting of results; and”;
 2 and

3 (2) in subsection (i), by striking “such sums”
 4 and all that follows through the period at the end
 5 and inserting “\$15,000,000 for fiscal year 2008 and
 6 such sums as may be necessary for each of the fiscal
 7 years 2009 through 2012.”.

8 **SEC. 5. EVALUATING THE EFFECTIVENESS OF NEWBORN-**
 9 **AND CHILD-SCREENING PROGRAMS.**

10 Section 1110 of the Public Health Service Act (42
 11 U.S.C. 300b–9) is amended by adding at the end the fol-
 12 lowing:

13 “(d) AUTHORIZATION OF APPROPRIATIONS.—There
 14 are authorized to be appropriated to carry out this section
 15 \$5,000,000 for fiscal year 2008 and such sums as may
 16 be necessary for each of the fiscal years 2009 through
 17 2012.”.

18 **SEC. 6. ADVISORY COMMITTEE ON HERITABLE DISORDERS**
 19 **IN NEWBORNS AND CHILDREN.**

20 Section 1111 of the Public Health Service Act (42
 21 U.S.C. 300b–10) is amended—

22 (1) in subsection (b)—

23 (A) in paragraph (1), by inserting “and
 24 grants awarded under section 399Z–1” before
 25 the semicolon;

1 (B) by redesignating paragraph (3) as
2 paragraph (6);

3 (C) in paragraph (2), by striking “and”
4 after the semicolon;

5 (D) by inserting after paragraph (2) the
6 following:

7 “(3) make systematic evidence-based and peer-
8 reviewed recommendations that include the heritable
9 disorders for which all newborns should be screened,
10 including secondary conditions that may be identi-
11 fied as a result of the laboratory methods used for
12 screening;

13 “(4) develop a model decision-matrix for new-
14 born screening program expansion, and periodically
15 update the recommended uniform screening panel,
16 as appropriate, based on such decision-matrix;

17 “(5) consider ways to ensure that States attain
18 the capacity to screen for the conditions described in
19 paragraph (3), and include in such consideration the
20 results of grant funding under section 1109; and”;

21 (E) in paragraph (6) (as so redesignated
22 by subparagraph (A)), by striking the period at
23 the end and inserting “, which may include rec-
24 ommendations, advice, or information dealing
25 with—

1 “(A) followup activities, including those
2 necessary to achieve rapid diagnosis in the
3 short term, and those that ascertain long-term
4 case management outcomes and appropriate ac-
5 cess to related services;

6 “(B) implementation, monitoring, and
7 evaluation of newborn screening activities, in-
8 cluding diagnosis, screening, follow-up, and
9 treatment activities;

10 “(C) diagnostic and other technology used
11 in screening;

12 “(D) the availability and reporting of test-
13 ing for conditions for which there is no existing
14 treatment;

15 “(E) conditions not included in the rec-
16 ommended uniform screening panel that are
17 treatable with Food and Drug Administration-
18 approved products;

19 “(F) minimum standards and related poli-
20 cies and procedures used by State newborn
21 screening programs, such as language and ter-
22 minology used by State newborn screening pro-
23 grams to include standardization of case defini-
24 tions and names of disorders for which newborn
25 screening tests are performed;

1 “(G) quality assurance, oversight, and
2 evaluation of State newborn screening pro-
3 grams, including ensuring that tests and tech-
4 nologies used by each State meet established
5 standards for detecting and reporting positive
6 screening results;

7 “(H) public and provider awareness and
8 education;

9 “(I) the cost and effectiveness of newborn
10 screening and medical evaluation systems and
11 intervention programs conducted by State-based
12 programs;

13 “(J) identification of the causes of, and
14 risk factors for heritable disorders; and

15 “(K) coordination of surveillance activities,
16 including standardized data collection and re-
17 porting, harmonization of laboratory definitions
18 for heritable disorders and testing results, and
19 confirmatory testing and verification of positive
20 results, in order to assess and enhance moni-
21 toring of newborn diseases.”; and

22 (2) in subsection (c)(2)—

23 (A) by redesignating subparagraphs (E),
24 (F) and (G) as subparagraphs (F), (H), and
25 (I);

1 (B) by inserting after subparagraph (D)
 2 the following:

3 “(E) the Commissioner of the Food and
 4 Drug Administration;”; and

5 (C) by inserting after subparagraph (F),
 6 as so redesignated, the following:

7 “(G) individuals with expertise in ethics
 8 who have worked and published material in the
 9 area of newborn screening;”; and

10 (3) by adding at the end the following:

11 “(d) DECISION ON RECOMMENDATIONS.—

12 “(1) IN GENERAL.—Not later than 180 days
 13 after the Advisory Committee issues a recommenda-
 14 tion pursuant to this section, the Secretary shall
 15 adopt or reject such recommendation.

16 “(2) PENDING RECOMMENDATIONS.—The Sec-
 17 retary shall adopt or reject any recommendation
 18 issued by the Advisory Committee that is pending on
 19 the date of enactment of the Newborn Screening
 20 Saves Lives Act of 2007 by not later than 180 days
 21 after the date of enactment of such Act.

22 “(3) DETERMINATIONS TO BE MADE PUBLIC.—
 23 The Secretary shall publicize any determination on
 24 adopting or rejecting a recommendation of the Advi-

1 sory Committee pursuant to this subsection, includ-
2 ing the justification for the determination.

3 “(e) ANNUAL REPORT.—Not later than 2 years after
4 the date of enactment of the Newborn Screening Saves
5 Lives Act of 2007, and each fiscal year thereafter, the Ad-
6 visory Committee shall—

7 “(1) publish a report on peer-reviewed newborn
8 screening guidelines in the United States;

9 “(2) submit such report to the appropriate com-
10 mittees of Congress, the Secretary, and the State de-
11 partments of health; and

12 “(3) disseminate such report on as wide a basis
13 as practicable, including through posting on the
14 internet clearinghouse established under section
15 1112.

16 “(f) CONTINUATION OF OPERATION OF COM-
17 MITTEE.—Notwithstanding section 14 of the Federal Ad-
18 visory Committee Act (5 U.S.C. App.), the Advisory Com-
19 mittee shall continue to operate during the 5-year period
20 beginning on the date of enactment of the Newborn
21 Screening Saves Lives Act of 2007.

22 “(g) AUTHORIZATION OF APPROPRIATIONS.—There
23 are authorized to be appropriated to carry out this sec-
24 tion—

25 “(1) \$1,000,000 for fiscal year 2008; and

1 “(2) such sums as may be necessary for each
2 of the fiscal years 2009 through 2012.”.

3 **SEC. 7. INFORMATION CLEARINGHOUSE.**

4 Part A of title XI of the Public Health Service Act
5 (42 U.S.C. 300b–1 et seq.) is amended by adding at the
6 end the following:

7 **“SEC. 1112. CLEARINGHOUSE OF NEWBORN SCREENING IN-**
8 **FORMATION.**

9 “(a) IN GENERAL.—The Secretary, acting through
10 the Administrator of the Health Resources and Services
11 Administration (referred to in this part as the ‘Adminis-
12 trator’), in consultation with the Director of the Centers
13 for Disease Control and Prevention and the Director of
14 the National Institutes of Health, shall establish and
15 maintain a central clearinghouse of current educational
16 and family support and services information, materials, re-
17 sources, research, and data on newborn screening to—

18 “(1) enable parents and family members of
19 newborns, health professionals, industry representa-
20 tives, and other members of the public to increase
21 their awareness, knowledge, and understanding of
22 newborn screening;

23 “(2) increase awareness, knowledge, and under-
24 standing of newborn diseases and screening services

1 for individuals wanting to have children and expect-
2 ant families; and

3 “(3) develop and maintain current data on
4 quality indicators to measure performance of new-
5 born screening, such as false-positive rates and other
6 quality indicators as determined by the Advisory
7 Committee under section 1111.

8 “(b) INTERNET AVAILABILITY.—The Secretary, act-
9 ing through the Administrator, shall ensure that the clear-
10 inghouse described under subsection (a)—

11 “(1) is available on the Internet;

12 “(2) includes an interactive forum;

13 “(3) is updated on a regular basis, but not less
14 than quarterly; and

15 “(4) provides—

16 “(A) links to Government-sponsored, non-
17 profit, and other Internet websites of labora-
18 tories as determined appropriate by the Sec-
19 retary that have demonstrated expertise in new-
20 born screening that supply research-based infor-
21 mation on newborn screening tests currently
22 available throughout the United States;

23 “(B) information about newborn conditions
24 and screening services available in each State
25 from laboratories certified under subpart 2 of

1 part F of title III, including information about
 2 supplemental screening that is available but not
 3 required, in the State where the infant is born;

4 “(C) current research on both treatable
 5 and not-yet treatable conditions for which new-
 6 born screening tests are available;

7 “(D) the availability of Federal funding for
 8 newborn and child screening for heritable dis-
 9 orders including grants authorized under the
 10 Newborn Screening Saves Lives Act of 2007;
 11 and

12 “(E) other relevant information as deter-
 13 mined appropriate by the Secretary.

14 “(c) NONDUPLICATION.—In developing the clearing-
 15 house under this section, the Secretary shall ensure that
 16 such clearinghouse minimizes duplication and supple-
 17 ments, not supplants, existing information sharing efforts.

18 “(d) AUTHORIZATION OF APPROPRIATIONS.—There
 19 are authorized to be appropriated to carry out this sec-
 20 tion—

21 “(1) \$2,500,000 for fiscal year 2008; and

22 “(2) such sums as may be necessary for each
 23 of the fiscal years 2009 through 2012.”.

1 **SEC. 8. LABORATORY QUALITY AND SURVEILLANCE.**

2 Part A of title XI of the Public Health Service Act
3 (42 U.S.C. 300b–1 et seq.), as amended by section 7, is
4 further amended by adding at the end the following:

5 **“SEC. 1113. LABORATORY QUALITY.**

6 “(a) IN GENERAL.—The Secretary, acting through
7 the Director of the Centers for Disease Control and Pre-
8 vention and in consultation with the Advisory Committee
9 on Heritable Disorders in Newborns and Children estab-
10 lished under section 1111, shall provide for—

11 “(1) quality assurance for laboratories involved
12 in screening newborns and children for heritable dis-
13 orders, including quality assurance for newborn-
14 screening tests, performance evaluation services, and
15 technical assistance and technology transfer to new-
16 born screening laboratories to ensure analytic valid-
17 ity and utility of screening tests; and

18 “(2) population-based pilot testing for new
19 screening tools for evaluating use on a mass scale.

20 “(b) AUTHORIZATION OF APPROPRIATIONS.—For the
21 purpose of carrying out this section, there are authorized
22 to be appropriated \$5,000,000 for fiscal year 2008 and
23 such sums as may be necessary for each of the fiscal years
24 2009 through 2012.

1 **“SEC. 1114. SURVEILLANCE PROGRAMS FOR HERITABLE**
2 **DISORDERS SCREENING.**

3 “(a) IN GENERAL.—The Secretary, acting through
4 an Interagency Group consisting of the Director of the
5 Agency for Healthcare Research and Quality, the Director
6 of the Centers for Disease Control and Prevention, the Ad-
7 ministrator, and the Director of the National Institutes
8 of Health, shall build upon existing activities and infra-
9 structure to carry out programs—

10 “(1) to collect, analyze, and make available data
11 on the heritable disorders recommended by the Advi-
12 sory Committee on Heritable Disorders in Newborns
13 and Children established under section 1111, includ-
14 ing data on the incidence and prevalence of, as well
15 as poor health outcomes resulting from, such dis-
16 orders;

17 “(2) to operate regional centers for the conduct
18 of applied epidemiological research on effective inter-
19 ventions for such disorders for the prevention of
20 poor health outcomes;

21 “(3) to provide information and education to
22 the public on effective interventions for the preven-
23 tion of poor health outcomes resulting from such dis-
24 orders; and

25 “(4) to conduct research on and to promote the
26 prevention of poor health outcomes resulting from

1 such disorders, and secondary health conditions
2 among individuals with such disorders.

3 “(b) GRANTS AND CONTRACTS.—

4 “(1) IN GENERAL.—In carrying out subsection
5 (a), the Secretary may make grants to and enter
6 into contracts with public and nonprofit private enti-
7 ties.

8 “(2) SUPPLIES AND SERVICES IN LIEU OF
9 AWARD FUNDS.—

10 “(A) IN GENERAL.—Upon the request of a
11 recipient of an award of a grant or contract
12 under paragraph (1), the Secretary may, sub-
13 ject to subparagraph (B), provide supplies,
14 equipment, and services for the purpose of aid-
15 ing the recipient in carrying out the purposes
16 for which the award is made and, for such pur-
17 poses, may detail to the recipient any officer or
18 employee of the Department of Health and
19 Human Services.

20 “(B) REDUCTION.—With respect to a re-
21 quest described in subparagraph (A), the Sec-
22 retary shall reduce the amount of payments
23 under the award involved by an amount equal
24 to the costs of detailing personnel and the fair
25 market value of any supplies, equipment, or

1 services provided by the Secretary. The Sec-
2 retary shall, for the payment of expenses in-
3 curred in complying with such request, expend
4 the amounts withheld.

5 “(3) APPLICATION FOR AWARD.—The Secretary
6 may make an award of a grant or contract under
7 paragraph (1) only if an application for the award
8 is submitted to the Secretary and the application is
9 in such form, is made in such manner, and contains
10 such agreements, assurances, and information as the
11 Secretary determines to be necessary to carry out
12 the purposes for which the award is to be made.

13 “(c) REPORTS TO CONGRESS.—

14 “(1) IN GENERAL.—Subject to paragraph (2),
15 the Secretary shall submit to the relevant commit-
16 tees of Congress reports—

17 “(A) containing information under para-
18 graph (1) that is specific to various racial, eth-
19 nic, and socioeconomic groups;

20 “(B) containing an assessment of the ex-
21 tent to which various approaches of preventing
22 heritable disorders and secondary health condi-
23 tions among individuals with such disorders
24 have been effective;

1 “(C) describing the activities carried out
2 under this section;

3 “(D) containing information on the inci-
4 dence and prevalence of individuals living with
5 heritable disorders, information on the health
6 status of individuals with such disorders includ-
7 ing the extent to which such disorders have con-
8 tributed to the incidence and prevalence of in-
9 fant mortality, information on any health dis-
10 parities experienced by such individuals, and
11 recommendations for improving the health and
12 wellness and quality of life of such individuals;

13 “(E) containing a summary of rec-
14 ommendations from all heritable disorders re-
15 search conferences sponsored by the Centers for
16 Disease Control and Prevention; and

17 “(F) containing any recommendations of
18 the Secretary regarding this section.

19 “(2) TIMING OF REPORTS.—The Secretary shall
20 submit—

21 “(A) an interim report that includes the
22 information described in paragraph (1), not
23 later than 30 months after the date on which
24 the first grant funds are awarded under this
25 section; and

1 “(B) a subsequent report that includes the
2 information described in paragraph 1, not later
3 than 60 months after the date on which the
4 first grant funds are awarded under this sec-
5 tion.

6 “(d) APPLICABILITY OF PRIVACY LAWS.—The provi-
7 sions of this section shall be subject to the requirements
8 of section 552a of title 5, United States Code. All Federal
9 laws relating to the privacy of information shall apply to
10 the data and information that is collected under this sec-
11 tion.

12 “(e) COORDINATION.—

13 “(1) IN GENERAL.—In carrying out this sec-
14 tion, the Secretary shall coordinate, to the extent
15 practicable, programs under this section with pro-
16 grams on birth defects and developmental disabilities
17 authorized under section 317C.

18 “(2) PRIORITY IN GRANTS AND CONTRACTS.—
19 In making grants and contracts under this section,
20 the Secretary shall give priority to entities that dem-
21 onstrate the ability to coordinate activities under a
22 grant or contract made under this section with exist-
23 ing birth defects surveillance activities.

24 “(f) AUTHORIZATION OF APPROPRIATIONS.—For the
25 purpose of carrying out this section, there are authorized

1 to be appropriated \$15,000,000 for fiscal year 2008 and
 2 such sums as may be necessary for each of the fiscal years
 3 2009 through 2012.”.

4 **SEC. 9. GRANTS.**

5 Part A of title XI of the Public Health Service Act
 6 (42 U.S.C. 300b–1 et seq.), as amended by section 8, is
 7 further amended by adding at the end the following:

8 **“SEC. 1115. GRANTS.**

9 “(a) AUTHORIZATION OF GRANT PROGRAM.—

10 “(1) IN GENERAL.—From funds appropriated
 11 under subsection (h), the Secretary, acting through
 12 the Administrator and in consultation with the Advi-
 13 sory Committee, shall award grants to eligible enti-
 14 ties to—

15 “(A) enable such entities to develop and
 16 deliver educational programs about newborn
 17 screening to parents, families, and patient advo-
 18 cacy and support groups, such educational ma-
 19 terials accompanying such educational pro-
 20 grams to be provided at appropriate literacy
 21 levels; and

22 “(B) enable such entities to establish,
 23 maintain, and operate a system to assess and
 24 coordinate treatment relating to congenital, ge-
 25 netic, and metabolic disorders.

1 “(2) AWARENESS OF THE AVAILABILITY OF
2 PROGRAMS.—To the extent practicable, the Sec-
3 retary shall make relevant health care providers
4 aware of the availability of the educational programs
5 supported pursuant to paragraph (1).

6 “(b) APPLICATION.—An eligible entity that desires to
7 receive a grant under this section shall submit an applica-
8 tion to the Secretary at such time, in such manner, and
9 accompanied by such information as the Secretary may
10 require.

11 “(c) SELECTION OF GRANT RECIPIENTS.—

12 “(1) IN GENERAL.—Not later than 120 days
13 after receiving an application under subsection (b),
14 the Secretary, after considering the approval factors
15 under paragraph (2), shall determine whether to
16 award the eligible entity a grant under this section.

17 “(2) APPROVAL FACTORS.—

18 “(A) REQUIREMENTS.—An application
19 submitted under subsection (b) may not be ap-
20 proved by the Secretary unless the application
21 contains assurances that the eligible entity—

22 “(i) will use grant funds only for the
23 purposes specified in the approved applica-
24 tion and in accordance with the require-
25 ments of this section; and

1 “(ii) will establish such fiscal control
2 and fund accounting procedures as may be
3 necessary to assure proper disbursement
4 and accounting of Federal funds paid to
5 the eligible entity under the grant.

6 “(B) EXISTING PROGRAMS.—Prior to
7 awarding a grant under this section, the Sec-
8 retary shall—

9 “(i) conduct an assessment of existing
10 educational resources and training pro-
11 grams and coordinated systems of followup
12 care with respect to newborn screening;
13 and

14 “(ii) take all necessary steps to mini-
15 mize the duplication of the resources and
16 programs described in clause (i) and en-
17 sure that funding under this section will
18 supplement, not supplant, existing funding
19 for such activities.

20 “(d) COORDINATION.—The Secretary shall take all
21 necessary steps to coordinate programs funded with
22 grants received under this section and to coordinate with
23 existing newborn screening activities.

24 “(e) USE OF GRANT FUNDS.—

1 “(1) IN GENERAL.—An eligible entity that re-
2 ceives a grant under this section may use the grant
3 funds—

4 “(A) for purposes of grants under sub-
5 section (a)(1)(A), to develop and deliver to par-
6 ents, families, and patient advocacy and sup-
7 port groups, educational programs about new-
8 born screening that include information on—

9 “(i) what newborn screening is and
10 how it is performed;

11 “(ii) who performs newborn screening;

12 “(iii) where newborn screening is per-
13 formed;

14 “(iv) the disorders for which the State
15 requires newborns to be screened;

16 “(v) different options for newborn
17 screening for disorders other than those in-
18 cluded by the State in the mandated new-
19 born screening program;

20 “(vi) the meaning of various screening
21 results, including the possibility of false
22 positive and false negative findings;

23 “(vii) the prevalence and risk of new-
24 born disorders, including the increased risk

1 of disorders that may stem from family
2 history;

3 “(viii) coordinated systems of followup
4 care after newborns are screened; and

5 “(ix) other items to carry out the pur-
6 pose described in subsection (a)(1) as de-
7 termined appropriate by the Secretary; and

8 “(B) for purposes of grants under sub-
9 section (a)(1)(B), to—

10 “(i) expand on existing procedures
11 and systems, where appropriate and avail-
12 able, for the timely reporting of newborn
13 screening results to individuals, families,
14 primary care physicians, and appropriate
15 subspecialists such as in congenital, ge-
16 netic, and metabolic disorders;

17 “(ii) coordinate ongoing followup
18 treatment with individuals, families, pri-
19 mary care physicians, and appropriate sub-
20 specialists such as in congenital, genetic,
21 and metabolic disorders after a newborn
22 receives an indication of the presence or in-
23 creased risk of a disorder on a screening
24 test;

1 “(iii) ensure the seamless integration
2 of confirmatory testing, tertiary care med-
3 ical services, comprehensive genetic serv-
4 ices including genetic counseling, and in-
5 formation about Food and Drug Adminis-
6 tration-approved treatments as well as ac-
7 cess to developing therapies by participa-
8 tion in approved clinical trials involving the
9 primary health care of the infant;

10 “(iv) analyze data, if appropriate and
11 available, collected from newborn
12 screenings to identify populations at risk
13 for disorders affecting newborns, examine
14 and respond to health concerns, recognize
15 and address relevant environmental, behav-
16 ioral, socioeconomic, demographic, and
17 other relevant risk factors;

18 “(v) collect, analyze and report data
19 on the costs, benefits and effectiveness of
20 such tests; and

21 “(vi) carry out such other activities as
22 the Secretary may determine necessary.

23 “(f) REPORTS TO CONGRESS.—

1 “(1) IN GENERAL.—Subject to paragraph (2),
2 the Secretary shall submit to the relevant commit-
3 tees of Congress reports—

4 “(A) evaluating the effectiveness and the
5 impact of the grants awarded under this sec-
6 tion—

7 “(i) in promoting newborn screen-
8 ing—

9 “(I) education and resources for
10 families; and

11 “(II) education, resources, and
12 training for health care professionals;

13 “(ii) on the successful diagnosis and
14 treatment of congenital, genetic, and meta-
15 bolic disorders; and

16 “(iii) on the continued development of
17 coordinated systems of followup care after
18 newborns are screened;

19 “(B) describing and evaluating the effec-
20 tiveness of the activities carried out with grant
21 funds received under this section; and

22 “(C) that include recommendations for
23 Federal, State, and local actions to support—

24 “(i) education and training in new-
25 born screening; and

1 “(ii) followup care after newborns are
2 screened.

3 “(2) TIMING OF REPORTS.—The Secretary shall
4 submit—

5 “(A) an interim report that includes the
6 information described in paragraph (1), not
7 later than 30 months after the date on which
8 the first grant funds are awarded under this
9 section; and

10 “(i) a subsequent report that includes
11 the information described in paragraph
12 (1), not later than 60 months after the
13 date on which the first grant funds are
14 awarded under this section.

15 “(g) ELIGIBLE ENTITY.—In this section, the term
16 ‘eligible entity’ means—

17 “(1) a State or a political subdivision of a
18 State;

19 “(2) a consortium of 2 or more States or polit-
20 ical subdivisions of States;

21 “(3) a territory;

22 “(4) an Indian tribe or a hospital or outpatient
23 health care facility of the Indian Health Service; or

24 “(5) other entities with appropriate expertise in
25 newborn screening, as determined by the Secretary.

1 “(h) AUTHORIZATION OF APPROPRIATIONS.—There
2 is authorized to be appropriated to carry out this section—

3 “(1) \$10,000,000 for fiscal year 2008; and

4 “(2) such sums as may be necessary for each
5 of fiscal years 2009 through 2012.”.

6 **SEC. 10. CONTINGENCY PLANNING.**

7 Part A of title XI of the Public Health Service Act
8 (42 U.S.C. 300b–1 et seq.), as amended by section 9, is
9 further amended by adding at the end the following:

10 **“SEC. 1116. NATIONAL CONTINGENCY PLAN FOR NEWBORN**
11 **SCREENING.**

12 “(a) IN GENERAL.—Not later than 180 days after
13 the date of enactment of this section, the Secretary, acting
14 through the Director of the Centers for Disease Control
15 and Prevention and in consultation with the Administrator
16 and State departments of health (or related agencies),
17 shall develop a national contingency plan for newborn
18 screening for use by a State, region, or consortia of States
19 in the event of a public health emergency.

20 “(b) CONTENTS.—The contingency plan developed
21 under subsection (a) shall include a plan for—

22 “(1) the collection and transport of specimens;

23 “(2) the shipment of specimens to State new-
24 born screening laboratories;

25 “(3) the processing of specimens;

1 “(4) the reporting of screening results to physi-
2 cians and families;

3 “(5) the diagnostic confirmation of positive
4 screening results;

5 “(6) ensuring the availability of treatment and
6 management resources;

7 “(7) educating families about newborn screen-
8 ing; and

9 “(8) carrying out other activities determined
10 appropriate by the Secretary.

11 **“SEC. 1117. HUNTER KELLY RESEARCH PROGRAM.**

12 “(a) ADDITIONAL NEWBORN SCREENING TESTS
13 GRANTS.—

14 “(1) IN GENERAL.—The Secretary, in conjunc-
15 tion with the Director of the National Institutes of
16 Health and taking into consideration the rec-
17 ommendations of the Advisory Committee, shall es-
18 tablish a research program (to be known as ‘Hunter
19 Kelly Newborn Screening Research Program’) by ex-
20 panding, carrying out, and coordinating research
21 in—

22 “(A) identifying, developing, and testing
23 the most promising new screening technologies,
24 in order to improve already existing screening
25 tests, which may include tests for Krabbe Dis-

1 ease and Insulin Dependent Diabetes Mellitus,
 2 and Turner Syndrome, increase the specificity
 3 of newborn screening, and expand the number
 4 of conditions for which screening tests are
 5 available;

6 “(B) experimental treatments and disease
 7 management strategies for additional newborn
 8 conditions, and other genetic, metabolic, hor-
 9 monal and/or functional conditions that can be
 10 detected through newborn screening for which
 11 treatment is not yet available; and

12 “(C) other activities that would improve
 13 newborn screening, as identified by the Direc-
 14 tor.

15 “(2) ADDITIONAL NEWBORN CONDITION.—For
 16 purposes of this subsection, the term ‘additional
 17 newborn condition’ means any condition that is not
 18 one of the core conditions designated by the Advi-
 19 sory Committee.

20 “(b) FUNDING.—In carrying out the research pro-
 21 gram under this section, the Secretary and the Director
 22 shall ensure that entities receiving funding through the
 23 program will provide assurances, as practicable, that such
 24 entities will work in consultation with the appropriate
 25 State departments of health, and, as practicable, focus

1 their research on screening technology not currently per-
2 formed in the States in which the entities are located, and
3 the conditions on the uniform screening panel (or the
4 standard test existing on the uniform screening panel).

5 “(c) MONITORING AND RESULTS.—The Director
6 shall—

7 “(1) monitor and report on the activities result-
8 ing from any funding distributed under this section;
9 and

10 “(2) on an annual basis—

11 “(A) publish and disseminate the results of
12 such monitoring on as wide a basis as is prac-
13 ticable, which may include incorporation of
14 these results in other newborn screening reports
15 and posting on the Internet Clearinghouse es-
16 tablished under section 1112;

17 “(B) submit to the relevant committees of
18 Congress the results of such evaluation, which
19 may include incorporation of such results in
20 other newborn screening reports being sub-
21 mitted to Congress.

22 “(d) NONDUPLICATION.—In carrying out programs
23 under this section, the Secretary shall minimize duplica-
24 tion and supplement, not supplant, existing efforts of the
25 type carried out under this section.

1 “(e) PEER REVIEW.—Nothing in this section shall be
2 construed to interfere with the scientific peer-review proc-
3 ess at the National Institutes of Health.

4 “(f) AUTHORIZATION OF APPROPRIATIONS.—There
5 are authorized to be appropriated to carry out this sec-
6 tion—

7 “(1) \$7,000,000 for fiscal year 2008; and

8 “(2) such sums as may be necessary for fiscal
9 years 2009 through 2012.”.

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